Appl. No. : 09/829,631
Filed : April 10, 2001

REMARKS

Claims 17-28, as re-numbered by the Patent Office, are pending in the application. Claim 17 is currently amended. No claims have been added or canceled. Additionally, per http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/benefitclaims.pdf, the specification has been amended to include a proper claim to priority. Reexamination and reconsideration of the application, as amended, are respectfully requested.

Under International and Domestic Law, The Instant Application Constitutes a Continuation Application

As filed, the instant application constitutes a continuation application, not a continuation-in-part application. The rule under MPEP 201.08 is that a continuation-in-part application is an application that discloses new matter not disclosed in the prior application. The exhibits show that the instant application discloses subject matter disclosed verbatim in 08/428,242, which is the national stage filing of PCT/US93/10296, because the instant application minus Claims 1-16 is a virtual photocopy of 08/428,242 minus the PCT Article 34 Claims 1-37 (except for the addition of SEQ ID NOs).

- Attached as Exhibit 1 is the St-B17 Serotonin Receptor Family Tree;
- Attached as Exhibit 2 is a copy of 07/970,338 filed Oct 26, 1992, having Claims 1-38;
- Attached as Exhibit 3 is a copy of PCT/US93/10296 filed Oct 26, 1993, which is a continuation-in-part of 07/970,338, published as WO94/10310 on May 11, 1994, having Claims 1-38;
- Attached as Exhibit 4 is a copy of "Transmittal Letter to the United States Designated/Elected Office (DO/EO/US) Concerning a Filing Under 35 USC 371" and a copy of the International Preliminary Examination Report with annexes thereto, i.e., amendments made under PCT Article 34, in 08/428,242 filed Sep 18, 1995, which is the U.S. National Stage of PCT/US93/10296. A statement of incorporation by reference would be improper because 08/428,242 *is* the national stage filing of PCT/US93/10296. Under the authority of PCT Article 34

and 37 CFR §1.495, the PCT Article 34 Claims 1-37 have effect in all elected Offices and *serve as the basis for examination* by the elected Offices; and

- Attached as Exhibit 5 is a copy of the instant application (and Transmittal Letter containing statement of incorporation by reference of prior 08/428,242).

As the exhibits show, the instant application discloses subject matter disclosed verbatim in 08/428,242, which is the national stage filing of PCT/US93/10296, because the instant application minus Claims 1-16 is a virtual photocopy of 08/428,242 minus the PCT Article 34 Claims 1-37 (except for the addition of SEQ ID NOs). Citing no authority whatsoever, the Patent Office takes the position that the substitution of new Claims 1-16 in the instant application for the PCT Article 34 Claims 1-37 in 08/428,242 transforms the instant application from a continuation application into a continuation-in-part application. Under this reasoning, the substitution of the PCT Article 34 Claims 1-37 in 08/428,242 for original Claims 1-38 in PCT/US93/10296 would transform 08/428,242 into a continuation-in-part application of PCT/US93/10296, which is incorrect because (1) 08/428,242 *is* the national stage filing of PCT/US93/10296), and (2) under the authority of PCT Article 34 and 37 CFR §1.495, the PCT Article 34 Claims have effect in all elected Offices and *serve as the basis for examination* by the elected Offices. In sum, there is no basis in law or logic that the substitution of new Claims 1-16 in the instant application for the PCT Article 34 Claims 1-37 in 08/428,242 transforms the instant application from a continuation application into a continuation-in-part application. (The Patent Office has other recourse, e.g., to reject the claims under the written description requirement of 35 USC § 112 and require the claims to be canceled.) Because the instant application minus Claims 1-16 is a virtual photocopy of 08/428,242 minus the PCT Article 34 Claims 1-37, the instant application discloses subject matter disclosed verbatim in 08/428,242 and does not disclose new matter. Therefore the instant application constitutes a continuation application, not a continuation-in-part application.

Under 35 USC § 112/1 and 35 USC § 102, the Instant Claims are Patentable to Applicant

The invention relates to the St-B17 serotonin receptor, (WO94/10310 at 3:2-5 and original Claim 1; 07/970,338 at 3:28-32 and original Claim 1) defined as having a unique pharmacology and <50% homology with previously cloned 5-HT (i.e., serotonin) receptors (WO94/10310 at 6:37-7:5; 07/970,338 at 7:36-8:5). The unique pharmacology is defined as exhibiting high affinity binding for the atypical and typical anti-psychotics clozapine and loxapine and several tricyclic anti-depressant drugs (i.e., amoxipine, clomiprimine, and amitriptyline) as determined by having a Ki value under 100 nM (WO94/10310 at 19:1-5; 07/970,338 at 20:7-12). Within the transmembrane domains, the St-B17 serotonin receptor exhibited homologies of 41%, 40%, 39%, 38%, 37%, and 36% with 5-HT2, 5-HT1D, 5-HT1C, 5-HT1B, 5-HT1A, and 5-HT1E serotonin receptors, respectively (WO94/10310 at 12: 22-24; 07/970,338 at 13:31-34). From the sequence dissimilarities, the previously cloned serotonin receptors cannot be identical to the St-B17 serotonin receptor of the invention.

The Patent Office rejected the claims under 35 USC §112, first paragraph, and 35 USC § 102 as lacking support for the definition in the preamble and thus creating patentability-defeating intervening art. The definition in the preamble has been deleted, but the definition has support as explained below and can optionally be added back into the preamble. Under MPEP 2111, however, it is unnecessary to add back the definition into the preamble to distinguish the St-B17 serotonin receptor from the previously cloned serotonin receptors, because the definition of the St-B17 serotonin receptor is to be consistent with applicant's disclosure. The citations from WO94/10310 and 07/970,338 show that applicant's disclosure contemplated that the St-B17 serotonin receptors of rat, human, and other species would act as a class and be defined as having the unique pharmacology formerly recited in the preamble:

- "One embodiment of the present invention is the isolated mammalian serotonin receptor protein St-B17. Preferably this receptor protein is human. The present invention also encompasses species variations of the St-B17 receptor." WO94/10310 at 3:2-5; and 07/970,338 at 3:28-32.
- "The unique pharmacology together with the relatively low level of homology (<50%) of St-B17 with previously cloned 5-HT receptor subtypes

indicates that this receptor does not belong to any of the previously defined 5-HT1 - 5HT4 subcategories of 5-HT receptors." WO94/10310 at 6:37-7:5; and 07/970,338 at 7:36-8:5.

- "The present invention includes isolated St-B17 serotonin receptors from rats, humans, other mammals, and other vertebrates." WO94/10310 at 8:16-18; and 07/970,338 at 9:16-22.

- "Within the transmembrane regions, St-B17$_3$ exhibited homologies of 41%, 40%, 39%, 38%, 37%, and 36% with 5-HT2, 5-HT1D, 5-HT1C, 5-HT1B, 5-HT1A, and 5-HT1E receptors, respectively." WO94/10310 at 12: 22-24; and 07/970,338 at 13:31-34.

- "These initial binding data would thus suggest that St-B17 encodes a 5-HT receptor subtype." WO94/10310 at 18:14-16; and 07/970,338 at 19:19-21.

- "Examination of the rank order of potency for a variety of serotonergic agents reveals that the pharmacology of clone St-B17 does not correspond to any previously described serotonin receptor subtype." WO94/10310 at 18:24-27; and 07/970,338 at 19:30-33.

- "Interestingly, the atypical and typical anti-psychotics clozapine and loxapine, respectively, also exhibited high affinity for St-B17, as did several tricyclic anti-depressant drugs (i.e., amoxipine, clomiprimine, and amitriptyline) which all has Ki value under 100 nM." WO94/10310 at 19:1-5; and 07/970,338 at 20:7-12.

As the citations show, applicant's disclosure contemplated that the St-B17 serotonin receptors of rat, human, and other species would act as a class and be defined as having the unique pharmacology formerly recited in the preamble. Moreover, the prior art of Julius et al., Proc. Natl. Acad. Sci. USA 87:928, 1990 (attached) exemplifies the state of the art for serotonin receptors and shows that the 5HT2, 5HT1C, 5HT1A, and B2AR receptors were expected to act as a class, respectively, despite being cloned from rat for 5HT2 receptor, rat for 5HT1C receptor, human for 5HT1A receptor, and hamster for β-adrenergic receptor, respectively (FIG. 1). Consequently, from the citations in WO94/10310 and 07/970,338, and consistent with the state

of the art for serotonin receptors, there was every contemplation that the St-B17 serotonin receptors of rat, human, and other species would act as a class and be defined as having the unique pharmacology formerly recited in the preamble. Because the definition of the St-B17 serotonin receptor is to be consistent with applicant's disclosure, it is unnecessary to add back the definition into the preamble to distinguish the previously cloned serotonin receptors from the St-B17 serotonin receptor of the invention.

Additionally, Monsma et al., Molecular Pharmacology 43:320 (March 1993) and Ruat et al., Biochem Biophys Res Comm 193:268 (May 1993), described the cloning of the rat St-B17 serotonin receptor, which was published at a time *after* the Oct 26, 1992 priority date of the 07/970,338 application, which priority application described the cloning the rat St-B17 serotonin receptor and contemplated that the St-B17 serotonin receptors of rat, human, and other species would act as a class and be defined as having the unique pharmacology formerly recited in the preamble. Furthermore, Kohen et al., J. of Neurochemistry 66:47 (1996), described the cloning of the human St-B17 serotonin receptor and confirmed its unique pharmacology, which was published at a time *after* the Oct 26, 1993 priority date of the WO94/10310 application, which priority application supplemented the 07/970,338 application by adding a description of the cloning of the human St-B17 serotonin receptor. Because these scientific publications are not *prior* art, they cannot bar patentability of the present invention.

CONCLUSION

In view of the above, it is submitted that the claims are in condition for allowance. Reconsideration and withdrawal of all outstanding rejections are respectfully requested. Allowance of the claims at an early date is solicited. If any points remain that can be resolved by telephone, the

Examiner is invited to contact the undersigned at the below-given telephone number.

Respectfully submitted,

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Dated: 6/20/03

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